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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,313	06/22/2001	Ian Tomlinson	8039/1122	9556
29933	7590	03/23/2004	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,313

Applicant(s)

TOMLINSON ET AL.

Examiner

MY-CHAU T TRAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-117 is/are pending in the application.
- 4a) Of the above claim(s) 69-77 and 87-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-68 and 78-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 01/02/04 is acknowledged and entered. Claims 78 and 86 have been amended.
2. Applicant's response filed 09/8/03 has been considered.
3. Claims 1-55 are canceled by the amendment filed on 11/27/02.
4. Claims 56-117 are pending.

Election/Restrictions

5. Claims 69-77, and 87-117 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement filed on 11/27/02.

Priority

6. The previous Office Action, mailed 03/12/03, has acknowledgment applicant's claim for foreign priority based on two applications filed in United Kingdom on 10/25/2000 and 6/23/2000 and noted that applicant ***has not filed*** a certified copy of both applications, which are 0026099.2 (10/25/00) and 0015443.5 (6/23/00), as required by 35 U.S.C. 119(b). Since no certified copies of the two applications filed in United Kingdom as required by 35 U.S.C. 119(b) has been filed,

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applicant's claim for foreign priority is *denied until* the certified copies of the two applications filed in United Kingdom is submitted. Thus this application is denied the foreign priority dates of 10/25/2000 and 6/23/2000.

7. Applicant stated that they are currently requesting the certified copies of the two applications filed in United Kingdom in order to perfect the priority claim.

Drawings

8. The drawings were received on 09/08/03. These drawings are acceptable.
9. Claims 56-68, and 78-86 are treated on the merit in this Office Action.

Withdrawn Objections and /or Rejections

10. In view of applicant's amendments of claims 78 and 86, the previous objection has been withdrawn.
11. In view of applicant's arguments that "[B]uechler and Gordong taken alone or together do not teach at least teach two repertoires of heavy or light chain polypeptide molecules arranged in at least two series of continuous lines such that a plurality of members of the first repertoire are juxtaposed with a plurality of members of the second repertoire", the rejection of claims 56-61 and 78-86 under 35 USC 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of Gordon et al. (US Patent 5,486,452) has been withdrawn.

Maintained Rejections

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

13. Claims 56-66 and 78-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of Miller et al. (WO 99/39210).

Buechler et al. disclosed a method of producing a multivalent polypeptide display library that can be use as diagnostic reagents (col. 2, lines 17-18; col. 4, lines 20-24). The polypeptides comprise of a heavy or light chain polypeptide of V_H or V_L sequences (col. 10, lines 53-65).

The method of Buechler et al. does not expressly disclose that the polypeptides are applied onto a solid support.

Miller et al. disclose a method for determining the protein profile of a biological sample (pg. 5, lines 12-30 to pg. 6, lines 1-7). The method comprise of a primary array proteins wherein X_n is the coordinate along a first dimension of the array and Y_n is the coordinate along a second dimension of the array. Screening the primary array with a plurality of antibodies and preparing the secondary array of antibodies that bind specifically to the proteins of the primary array. Determining the protein in the biological sample by screening the secondary array with the biological.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polypeptides are applied onto a solid support by Miller et al.

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in the method of Buechler et al. One of ordinary skill in the art would have been motivated to include the polypeptides are applied onto a solid support in the method of Buechler et al. for the advantage of providing a multiple array screening systems that could be readily applied to an entire proteomes (Miller: pg. 4, lines 21-23). Since both Miller et al. and Buechler et al. disclose an immunoassay method based on antigen-antibody detection using fusion protein (Miller: pg. 5, lines 12-30 to pg. 6, lines 1-7; pg. 20, lines 4-12; Buechler: col. 8, lines 8-11).

Response to Arguments

14. Applicant's arguments directed to the above rejection were considered but they are not persuasive for the following reasons.

Applicant contends that “[B]uechler and Miller taken alone or together do not teach at least teach two repertoires of heavy or light chain polypeptide molecules arranged in at least two series of continuous lines such that a plurality of members of the first repertoire are juxtaposed with a plurality of members of the second repertoire” and thus the combination of Buechler and Miller is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combination of Buechler and Miller is obvious over the presently claimed invention. Buechler discloses the method of constructing libraries of antibody fragments comprising light or heavy chain for screening (col. 8, lines 8-11; col. 10, lines 53-65). Thus Buechler teach that two repertoires comprise heavy or light chain polypeptide molecules as claimed in the present method. Miller discloses the method of antibody screening using two high-density arrays (pg. 8, lines 15-22) wherein the primary array forms antigen-antibody complexes with elements of the secondary array (pg. 7, lines 16-20). Additionally, Miller defines “array” as a linear arrangements of antibodies (pg. 17, lines 5-7 and

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lines 17-19). Thus Miller teaches the arrangement of the two repertoires in a series of continuous lines such that the plurality of members of the first repertoire is juxtaposed with a plurality of members of the second repertoire. Therefore, the method combination of Buechler and Miller is obvious over the presently claimed method because it would provide the advantage of a multiple array screening systems that could be readily applied to an entire proteomes (Miller: pg. 4, lines 21-23). Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in the method combination of Buechler and Miller since it allows for a single step analysis of antibody screening and antibody specificity testing in a time effective and cost effective manner.

15. Claims 56-68 and 78-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler et al. (US Patent 6,057,098) in view of de Wildt et al. (*Nature biochemistry*, 2000, 18(27):989-994).

Buechler et al. disclosed a method of producing a multivalent polypeptide display library that can be use as diagnostic reagents (col. 2, lines 17-18; col. 4, lines 20-24). The polypeptides comprise of a heavy or light chain polypeptide of V_H or V_L sequences (col. 10, lines 53-65).

The method of Buechler et al. does not expressly disclose that the polypeptides are applied onto a solid support.

De Wildt et al. disclose a method for screening antibody-antigen interactions, whereby many antibodies are screened in parallel against many antigens, and the filter-screening techniques is applied to the ordered arrays of antibodies generated by robotic picking and gridding (pg. 989, lines 12-16). The method comprise of colonies of antibodies are picked into

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384 well plates and grown (pg. 993, lines 21-47). The colonies are then gridded in a 4x4 pattern onto a large square plate covered with a nitrocellulose filter. A second filter is coated with the ligand protein L. The first filter containing the antibodies colonies is transferred onto the plate covered with the second filter and antibody binding to the second filter is detected.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the polypeptides are applied onto a solid support as taught by De Wildt et al. in the method of Buechler et al. One of ordinary skill in the art would have been motivated to include the polypeptides are applied onto a solid support in the method of Buechler et al. for the advantage of providing a high-throughput screening of recombinant antibodies without "sticky" or cross-reactive colonies (De Wildt: abstract). Since both De Wildt et al. and Buechler et al. disclose an immunoassay method based on antigen-antibody detection ((De Wildt: pg. 989, lines 12-16; Buechler: col. 8, lines 8-11).

Response to Arguments

16. Applicant's argument(s) directed to the above rejection were considered but they are not persuasive for the following reasons.

Applicant alleges that "[B]uechler and deWildt taken alone or together do not teach at least teach two repertoires of heavy or light chain polypeptide molecules arranged in at least two series of continuous lines such that a plurality of members of the first repertoire are juxtaposed with a plurality of members of the second repertoire" and thus the combination of Buechler and Miller is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combination of Buechler and deWildt is obvious over the presently claimed invention. The method of Buechler discloses constructing

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libraries of antibody fragments comprising light or heavy chain for screening (col. 8, lines 8-11; col. 10, lines 53-65). Thus Buechler teach that two repertoires comprise heavy or light chain polypeptide molecules as claimed in the present method. DeWildt discloses the method of gridding in a 4x4 pattern on a first square filter (a row of spots) (pg. 993, right col., lines 27-30) and coating a second square filter (pg. 993, right col., lines 34-41). Then transferring the first filter onto the second filter (interaction of the antibodies on the first filter and the proteins on the second filter) (pg. 993, right col., lines 43-45). The specification on page 3 (lines 7-13) defined that "[T]he lines can be straight, substantially parallel lines, or curves, or combinations thereof; the only restriction is that all members of the first repertoire should be able to interact all members of the second repertoire. Examples of complementary configurations include straight parallel lines, disposed at an angle to straight parallel lines; *concentric circles* or polygons, used together with a star of radial lines". Thus deWildt teaches the arrangement of the two repertoires in a series of continuous lines such that the plurality of members of the first repertoire is juxtaposed with a plurality of members of the second repertoire. Therefore, the method combination of Buechler and deWildt is obvious over the presently claimed method because it would provide the advantage of a high-throughput screening of recombinant antibodies without "sticky" or cross-reactive colonies (De Wildt: abstract). Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in the method combination of Buechler and deWildt since it allows for a single step analysis of antibody screening and antibody specificity testing in a time effective and cost effective manner.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct

March 20, 2004



PADMASHRI PONNALURI
PRIMARY EXAMINER